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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,277	12/02/2008	Andrew R. Barron	11321-P080WOUS	2418

61060 7590 05/13/2011

WINSTEAD PC
P.O. BOX 50784
DALLAS, TX 75201

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/13/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/585,277	BARRON ET AL.
	Examiner	Art Unit
	Jeffrey E. Russel	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 July 2006 and 25 August 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070831*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The declaration filed December 2, 2008 is defective. Seven pages of declarations were submitted: 2 copies of a 3-page declaration signed by Inventor Barron, and a single signature page by Inventor Yang. Neither of the copies of the Barron declaration include a full list of inventors, i.e. neither mentions Inventor Yang and neither refers to an attached supplemental sheet listing additional inventors. The page numbers of these two copies of the Barron declaration also do not indicate that a supplemental sheet listing additional inventors should be expected. Concerning the single signature page by Inventor Yang, this page clearly does not satisfy the requirements of 37 CFR 1.63, e.g., does not identify the application to which it is directed, does not include a "reviews and understands" clause or a "duty to disclose" clause, does not include a complete list of inventors, and does not include the statutory declaration language.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

Amino acid sequences subject to the sequence disclosure rules are present in Figure 12 and at page 12, line 12, and page 13, line 4, of the specification. However, no Sequence Listing has been submitted.

Applicant must provide an original computer readable form (CRF) copy of the Sequence Listing, an original paper copy of the Sequence Listing as well as an amendment directing its

entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.821(f) and (g).

3. The drawings are objected to because SEQ ID NOS need to be inserted after the amino acid sequences recited in Figure 12. See 37 CFR 1.821(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

As an alternative to inserting SEQ ID NOS into Figure 12, it would be acceptable to insert SEQ ID NOS into the Brief Description of Figure 12 at page 4 of the specification.

4. The disclosure is objected to because of the following informalities: At paragraph [0007], line 4, "metals" is misspelled. Two different spellings of what appears to be the same word are present at, e.g., page 10, line 2 ("Fullerecine") and at paragraph [0048], line 1 ("Fullericine").

The different spellings should be reconciled here and throughout the specification. At paragraph [0052], line 6, and elsewhere in the specification, it is believed that "perperidine" is a misspelling for "piperidine". SEQ ID NOS must be inserted after the amino acid sequences appearing at page 12, line 12, and page 13, line 4. See 37 CFR 1.821(d). Appropriate correction is required.

5. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the phrase "typical biological conditions" at claim 1, line 3, is unclear. The word "typical" is a relative term, but no standard of reference has been provided with which to determine whether a particular biological condition is "typical" or not and therefore encompassed within the scope of the claim. The phrase could be interpreted as including, e.g., the acidic environment of the stomach, the internal environment of lysosomes, aerobic and anaerobic bacterial environments, fermentative environments, etc. Further, it is not clear if the phrase requires the R functionality to be hydrolysis-resistant under every typical biological condition (e.g., under both acidic and basic conditions), or if it is sufficient for the R functionality to be hydrolysis-resistant under a single typical biological condition (e.g., under either acidic or basic conditions). Claims 3, 17, and 20 are indefinite because they are incomplete. These claims recite compound numbers, but do not provide the actual chemical formulae for these compounds. As set forth in MPEP 2173.05(s), claims are to be complete in and of themselves, and incorporation by reference to a specific figure is permitted only where there is no other practical way to define the invention. Applicants have not demonstrated that it is not practical to insert the necessary formulae into the claims. Claim 11 is unclear because it recites that an amino acid residue further comprises at least one naturally occurring amino acid.

However, while compositions can further comprise additional components, one compound can not be said to comprise another compound. Further, to the extent that Applicants intend to recite that the amino acid residue of claim 10 is attached to another amino acid, then the compound is no longer an amino acid but rather is a peptide. For analogous reasons, claim 22 is also indefinite. Claim 12 is indefinite because it recites a "synthetic polymer comprising an amino acid composition of Claim 1". However, it seems likely that Applicants intend to claim the amino acids of claim 1 as part of a peptide/polypeptide/protein chain, in which case an amino acid of claim 1 (with unmodified N- and C-termini) would no longer be present. The reference to "and combinations thereof" at claim 12, line 3, is unclear, because no matter how peptide chains, polypeptides and/or proteins are joined together, the result is still a peptide chain, polypeptide and/or protein, i.e. the same individual members of the Markush group. At best, the recitation of "and combinations thereof" in claim 12 is redundant. Claim 13 is indefinite because it is grammatically non-sensical to recite that a protein can comprise a biological function. Proteins are comprised of atoms. It may be that Applicants intended to recite a protein "exhibiting" a biological function. The Markush group recited in claim 13 is also unclear because "antibody" is not a biological function, but rather is a type of protein. The interpretation of "structure-determining" in claim 14 is unclear. Every atom in a compound necessarily contributes to the structure of the compound and is therefore "structure-determining" to at least some extent. Claim 21 recites "amino acid residues that comprise an amino acid composition of Claim 1"; however, as noted above with respect to claim 10, amino acids and amino acid residues are different chemical entities, and amino acid residues can not be said to comprise amino acids.

6. Claims 10 and 11 are objected to because of the following informalities: In claim 10, "composition" should be inserted after "amino acid" (second occurrence) so as to be consistent with the terminology of the independent claim. Appropriate correction is required.

7. Claims 5-7 and 10-16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 1 recites a general formula in which the amine functionality and the carboxylic acid functionality are unprotected. However, dependent claims 5-7 require one or both of these functionalities to be protected. Accordingly, dependent claims 5-7 embrace compounds which are not embraced within the scope of the independent claim, and are therefore improper dependent claims. Independent claim 1 recites a general formula in which an amino group (H_2N) and a carboxylic acid group (C(O)-OH) are present. Dependent claim 10 is drawn to an amino acid "residue", which is defined in the art as an amino acid in which a hydrogen atom from the N-terminus and a hydroxyl group from the C-terminus are no longer present, typically because of further covalent modification at these sites. Such a residue would have the formula -HN-CH(R)-C(O)-. Accordingly, by comparing formulae, it can be seen that dependent claim 10 embraces compounds which are not embraced within the scope of the independent claim, and is therefore an improper dependent claim. Every dependent product claim (i.e. claims 11-16) which requires covalent modification of the general formula recited in independent claim is an improper dependent claim.

8. Claims 18-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. See MPEP § 608.01(n). Note that claim 18 is dependent upon both claim 17 and upon claim 1; and claim 21 is dependent upon both claim 17 and claim 1.

9. Applicant is advised that should claim 8 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 9 is identical in scope with claim 8, upon which it depends. Note that claim 9 recites both "radioactive species" and "non-radioactive species", which between them encompass every possible species of dopant.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by the Skiebe et al article (J. Chem. Soc. Chem. Comm., 1994, pages 335-336). The Skiebe et al article teaches compound 5 (see Scheme 1), which comprises a C-terminally protected lysine residue with buckminsterfullerene (C_{60}) attached to the lysine sidechain via an amide bond. Because

compound 5 of the Skiebe et al article possesses all of the structural features required by the rejected claims, because of the steric hindrance provided by the buckminsterfullerene substituent, and in view of the uncertainty as to the interpretation of "typical biological conditions" (see also the discussion of this term in the above rejection under 35 U.S.C. 112, second paragraph), compound 5 of the Skiebe et al article is deemed inherently to be "hydrolysis-resistant under typical biological conditions" to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between compound 5 of the Skiebe et al article and Applicants' claimed compound to shift the burden to Applicants to provide evidence that the claimed compound is unobviously different than compound 5 of the Skiebe et al article.

12. Claims 10-12, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 0 919 520 A2. (This reference was cited in the International Search Report, and accordingly a copy of the reference is not being provided with this action.) The European Patent Application '520, in Example 17, teaches poly-L-tyrosine with C_{60} fullerenes attached to the sidechains of the tyrosine residues. With respect to instant claim 14, any substituent present in a compound will necessarily affect the structure of the compound, and therefore the C_{60} fullerenes present in the compound of the European Patent Application '520 will inherently be "structure-determining".

13. Claims 10-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Sagman et al (U.S. Patent No. 7,758,889). Sagman et al teach a fullerene attached through a disulfide bond to the side chain of a cysteine residue present in an antibody. See Figures 7 and 8. With respect to instant claim 15, the drugs attached to the fullerene group in Figure 8 make the modified fullerene group a "reaction" pocket as required by Applicants' claim.

14. Claims 6, 7, 10-12, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by the Pantarotto et al article (J. A, Chem. Soc., Vol. 124, pages 12543-12549). The Pantarotto et al article teaches a glutamic acid residue protected at its N-terminus with Fmoc and modified at its sidechain with a fullerene derivative. See page 12544, column 2, compound 1. Because compound 1 of the Pantarotto et al article possesses all of the structural features required by the rejected claims, because of the steric hindrance provided by the fullerene substituent, and in view of the uncertainty as to the interpretation of "typical biological conditions" (see also the discussion of this term in the above rejection under 35 U.S.C. 112, second paragraph), compound 1 of the Pantarotto et al article is deemed inherently to be "hydrolysis-resistant under typical biological conditions" to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between compound 1 of the Pantarotto et al article and Applicants' claimed compound to shift the burden to Applicants to provide evidence that the claimed compound is unobviously different than compound 1 of the Pantarotto et al article. Compound 1 of the Pantarotto et al article is used to form enkephalin analogs and cationic antimicrobial peptides. See, e.g., the Abstract and page 12544, column 2, Table 1.

15. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by the Burley et al article (J. Org. Chem., Vol. 67, pages 8316-8330). The Burley et al article teaches compounds 11-13, which are glycine residues protected at their N- and C-termini and modified at their alpha-carbon with [60]fullerene. See page 8318, Scheme 2. Because compounds 11-13 of the Burley et al article possesses all of the structural features required by the rejected claims, because of the steric hindrance provided by the fullerene substituent, and in view of the uncertainty as to the interpretation of "typical biological conditions" (see also the discussion of this term in the above

rejection under 35 U.S.C. 112, second paragraph), compounds 11-13 of the Burley et al article are deemed inherently to be "hydrolysis-resistant under typical biological conditions" to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between compounds 11-13 of the Burley et al article and Applicants' claimed compound to shift the burden to Applicants to provide evidence that the claimed compound is unobviously different than compounds 11-13 of the Burley et al article.

16. Claims 1-4, 8, 9, and 17-22 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the claim objections set forth in this Office action.

The WO Patent Application 2004/091508, cited in the International Search Report, has been carefully considered, especially for the compound taught in Figure 11H. However, this compound is not supported, under the test of 35 U.S.C. 112, first paragraph, by the disclosure of provisional application 60/461,914, upon which the WO Patent Application '508 claims priority. Accordingly, the WO Patent Application '508's disclosure of the compound in figure 11H is not prior art under 35 U.S.C. 102 against the instant claims. For analogous reasons, U.S. Patent No. 7,163,956's disclosure of the compound in Figure 10H is not prior art under 35 U.S.C. 102 against the instant claims.

17. Concerning the Information Disclosure Statement filed August 31, 2007, only a single page of listed references was found with the submission. The heading for this page is marked "Sheet 2 of 2"; however, the examiner has been unable to locate any page marked "Sheet 1 of 2". If an additional page of listed references should have been present, it will have to be re-submitted.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
May 12, 2011